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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,870	11/01/2001	Joseph A. Sorge	25436/1552	1443

27495 7590 04/28/2003

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
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1637

8

DATE MAILED: 04/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



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Office Action Summary

Application No.

10/034,870

Applicant(s)

SORGE, JOSEPH A.

Examiner

Alexander H. Spiegler

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to Paper No. 6, filed on July 3, 2002. Currently, claims 1-18 are pending. This action is made NON-FINAL.

Information Disclosure Statement

2. The information disclosure statement of Paper No. 4 complies with CFR 1.97, 1.98, and M.P.E.P. 609, and has been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-2, 5, 7-8 and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauer et al. (USPN 5,789,166).

Bauer et al. teach a method for preparing a nucleic acid sample for an analytical procedure, said method comprising treating said sample with a substance that cleaves said template nucleic acid without substantially cleaving said synthetic nucleic acid (cols. 9-10). Bauer et al. also teaches that a nucleic acid sample generated from the amplification reaction (e.g., SSR, SDA) can be treated with a substance that cleaves said template nucleic acid without substantially cleaving said synthetic nucleic acid (cols. 2-4 and 8-12). Bauer et al. teaches that the substances can be one of many possible restriction enzymes, such as DpnI, Nan II, NmuD I,

Art Unit: 1637

NmuE I or need not be restriction enzymes, such as uracil N-glycosylase (cols. 9-10). Bauer et al. also teaches that the nucleic acid sample can come from *E. coli* (cols. 12-13).

5. Claims 1-3, 5, 7-8 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Yuan (USPN 6,376,210).

Yuan teaches a method of preparing a nucleic acid sample for DNA sequencing (following amplification), said method comprising treating said sample with a substance that cleaves said template nucleic acid without substantially cleaving said synthetic nucleic acid (cols. 56-7). Yuan teaches that the substance can be DpnI (cols. 56-7).

6. Claims 1-3, 5-9, and 11-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Carmichael et al. (USPN 6,376,210).

Carmichael teaches a transcription reaction wherein a nucleic acid sample is generated comprising template and synthetic RNA, the improvement whereby after the transcription reaction and immediately prior to the analysis of the RNA sample, said nucleic acid sample is treated with a substance that cleaves said template nucleic acid and does not substantially cleave the RNA (cols. 6-8, especially Example 4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKernan et al. (USPN 6,534,262), in view of Bauer et al. (USPN 5,789,166).

McKernan teaches that following a capillary sequencing reaction; it is advantageous to obtain a high quality nucleic acid product (e.g., a product void of unwanted components).

Specifically, McKernan states:

Many molecular biology applications, such as capillary electrophoresis, nucleotide sequencing, reverse transcription cloning and gene therapy protocols, which contemplate the transfection, transduction or microinjection of mammalian cells, require the isolation of high quality nucleic acid preparations. Quality is a particularly important factor for capillary electrophoresis for all sequencing methods and for gene therapy protocols...

Extension product quality is...a particularly critical consideration for capillary electrophoresis protocols. The isolation of high quality nucleic acid preparations from starting mixtures of diverse composition and complexity is a fundamental technique in molecular biology. (col. 1)

McKernan teaches that one of the unwarranted components that should be removed to ensure a high quality capillary sequencing product is template DNA (see for example, cols. 3, ln. 1-6, col. 4, 17-20, and cols. 12, 20-22). Therefore, McKernan teaches that it is advantageous to remove template DNA following a capillary sequencing reaction.

McKernan teaches that the removal of the template DNA can be accomplished by conventional methods (col. 20, ln. 45-48), however, does not teach "cleavage per se" of the template DNA.

However, Bauer teaches the removal of template DNA using a conventional method, e.g., treating a sample with a substance (e.g., restriction enzyme) that cleaves said template nucleic acid without substantially cleaving said synthetic nucleic acid (cols. 5 and 9-10). Bauer teaches that the use of a restriction enzyme allows the template DNA to be removed easily and more effective than previous methods used in the art (cols. 1-3, 5 and 10). Accordingly, Bauer teaches a conventional, easy and effective method for removing template DNA.

In view of the teachings of Bauer, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of purifying the capillary sequencing product of McKernan, so as to have included the steps of adding a restriction enzyme as taught by Bauer, in order to have achieved the benefit of providing a fast and effective means of removing template DNA, and therefore, providing a high quality product.

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer et al. (USPN 5,789,166) as applied to claims 1-2, 5, 7-8 and 10-17 above, and further in view of McClelland et al. (USPN 4,808,525).

The teachings of Bauer are presented above. Specifically, Bauer et al. teach a method for preparing a nucleic acid sample (from *E. coli*) for an analytical procedure, said method comprising treating said sample with a substance that cleaves said template nucleic acid without substantially cleaving said synthetic nucleic acid. Bauer does not specifically teach obtaining nucleic acid samples from dam+ *E. coli* cells.

However, McClelland teaches that Dpn I cleaves DNA from dam+ *E. coli* cells.

Therefore, in view of the teachings of McClelland, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Bauer to have used dam+ *E. coli* cells, in order to have achieved the benefit of providing an equally effective means of preparing a nucleic acid for mutagenesis.

Conclusion

10. No claims are allowable.


Correspondence

Art Unit: 1637

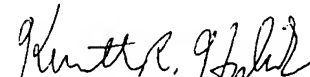
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alexander H. Spiegler
April 11, 2003


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/14/03